Scheduling Status:
S4

MOXIDROP
Moxifloxacin hydrochloride 5 mg/ml

Read all of this leaflet carefully before you use MOXIDROP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- MOXIDROP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MOXIDROP is and what it is used for
2. What you need to know before you use MOXIDROP
3. How to use MOXIDROP
4. Possible side effects
5. How to store MOXIDROP
6. Contents of the pack and other information

1. What MOXIDROP is and what it is used for

MOXIDROP eye drops are used for the treatment of infections of the eye (conjunctivitis) when caused by bacteria. The active ingredient is moxifloxacin an anti-infective belonging to a group of antibiotics called fluoroquinolones.

2. What you need to know before you use MOXIDROP

Do not use MOXIDROP:

- If you are hypersensitive (allergic) to moxifloxacin, to other quinolones or any of the other ingredients of MOXIDROP (listed in section 6).

Warnings and precautions

Take special care with MOXIDROP:

- Talk to your doctor or pharmacist: **If you experience an allergic reaction to MOXIDROP.**
- If you have been using MOXIDROP for a long time, it may lead to other infections.

- If you develop pain or swelling of the tendons (tendinitis) stop taking MOXIDROP. Tendon swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids.

- If you wear contact lenses – stop wearing your lenses if you have any signs or symptoms of an eye infection. Wear your glasses instead. Do not start wearing your lenses again until the signs and symptoms of the infection have cleared and until you have stopped using the medicine.

Children and adolescents

An infant less than four weeks old with ophthalmia neonatorum (is an eye infection that occurs within the first 30 days of life. It is caught during birth by contact with the mother's birth canal that is infected with a sexually transmitted disease) should receive suitable treatment for their condition, e.g. systemic treatment in cases caused by *Chlamydia trachomatis* or *Neisseria gonorrhoeae*.

Do not give MOXIDROP to children under 2 years of age for the treatment of *Chlamydia trachomatis*.

Other medicines and MOXIDROP

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

No specific drug-drug interaction studies were performed with MOXIDROP, they have been performed with oral products, where the systemic exposure is much higher as in the eye products.

MOXIDROP has no interaction with itraconazole, theophylline, warfarin, digoxin, oral contraceptives, probenecid, ranitidine, or glyburide when given together.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before you use MOXIDROP.

MOXIDROP should be used with caution when you are planning to become pregnant, during pregnancy and if you are breastfeeding your baby, because no studies have been performed to ensure the safety.

Driving and using machines

MOXIDROP can cause blurred vision or other visual disturbances for a short time just after use. Do not drive or use machines until your vision is clear.

It is not always possible to predict to what extent MOXIDROP may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which MOXIDROP affects you.

3. How to use MOXIDROP

Do not share medicines prescribed for you with any other person.

Always use MOXIDROP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If a drop misses your eye, try again.

The recommended dose is

1 drop in the affected eye or eyes, 3 times a day (in the morning, in the afternoon and at night).

Your doctor will tell you how long your treatment with MOXIDROP will last. Do not stop treatment early because the infection has not been cleared up and may start again.

If you have the impression that the effect of MOXIDROP is too strong or too weak, tell your doctor or pharmacist.

Directions:

Get the MOXIDROP bottle and stand in front of a mirror

Wash your hands

Twist off the cap

After cap is removed, if tamper evident snap collar is loose, remove before using the product

Hold the bottle, pointing down, between your thumb and fingers

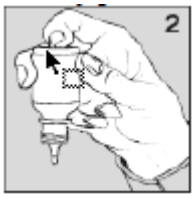
Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1)



Bring the bottle tip close to the eye. Use the mirror if it helps

Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops

Gently press the bottom of the bottle to release one drop of medicine at a time (picture 2)



After using MOXIDROP, press a finger into the corner of your eye, by the nose for 2 - 3 minutes (picture 3).



If you are using the drops in both eyes, **wash your hands before you repeat the steps for your other eye.** This will help prevent spreading the infection from one eye to the other.

Close the bottle cap firmly immediately after use.

If you use more MOXIDROP than you should

If you use more medicine than you should, rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.

If you forget to use MOXIDROP

Do not use a double dose to make up for forgotten individual doses. Continue with the next dose as planned.

If you stop using MOXIDROP

If you stop using MOXIDROP before the recommended time of dosage, the infection may not be cleared up and the infection may start again.

4. Possible side effects

MOXIDROP can have side effects.

Not all side effects reported for MOXIDROP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using MOXIDROP, please consult your healthcare provider for advice.

If any of the following happens, stop using MOXIDROP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth, tongue or throat, which may cause difficulty in swallowing or breathing, blueness of the skin.
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MOXIDROP. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- irregular heart rhythm

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- eye pain, eye irritation

Less frequent side effects

- decreased iron in blood
- headache
- an abnormal sensation, typically tingling or pricking ('pins and needles')
- dry eye, itchy eye, redness of the eye, eye surface inflammation or scarring, broken blood vessel in eye, abnormal eye sensation, corneal disorder, eyelid abnormality or inflammation, eye strain, inflammation or infection of the conjunctiva, blurred vision, itching, redness or swelling
- nose discomfort, feeling of a lump in the throat
- throat irritation
- vomiting
- bad taste
- abnormal liver blood tests

Unknown frequency of side effects

- infection in the eye, eye surface becomes cloudy, corneal swelling, deposits on the eye surface, increased pressure in eye, scratch on surface of eye, eye allergy, eye discharge, increased tear production, sensitivity to light
- shortness of breath
- nausea
- skin redness
- hives

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**Adverse drug reaction and product quality reporting**" on https://primaryreporting.who-umc.org/ZA (accessed through https://www.sahpra.org.za/ E-services).

5. How to store MOXIDROP

Store all medicine out of reach of children.

Store at or below 25 °C.

Do not use more than 30 days after opening. This is to prevent infections.

Keep the container tightly closed and in the outer carton

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

Return the expired medicine to your pharmacist for safe disposal.

6. Contents of the pack and other information

What MOXIDROP contains

The active ingredient is moxifloxacin. One ml of eye drops contains 5 mg of moxifloxacin (as moxifloxacin hydrochloride, 5,45 mg).

The other ingredients are sodium chloride, boric acid, sodium hydroxide (pH adjuster) and water for injections.

What MOXIDROP looks like and contents of the pack

MOXIDROP is a sterile, clear greenish yellow colour solution.

MOXIDROP is packaged in 5 ml round LDPE dropper bottle for both 3 ml and 5 ml presentations. The product is stoppered with white HDPE Screw Cap e-beam sterilised and LDPE droppers.

Pack size: box containing 1 bottle.

Holder of Certificate of Registration:

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